REMARKS/ARGUMENTS

Claims 1-31 were pending at the time of the mailing of the outstanding Office Action. Claims 16-25 and 30-31 have been withdrawn from consideration. By this amendment, the abstract has been amended to conform with the requirements of MPEP § 608.01 (6). No claims have been added, cancelled or amended.

In the Office Action of 8 June 2005, the Examiner objected to the abstract. Claims 1, 2, 5-13, 26-29 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 6,254,632 to Wu et al. (hereinafter "Wu"). Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as unpatentable over Wu. Claims 14 and 15 were rejected under 35 U.S.C. § 103(a) as unpatentable over Wu in view of U.S. Pat. No. 6,287,628 to Hossainy et al. (hereinafter "Hossainy").

To anticipate a claim, a reference must teach all elements of the claim (MPEP § 2131). The Examiner maintains that Wu discloses a stent having microdevices raised out from a base body to form microcannulae on the surface of the stent to penetrate into the vessel wall. The Examiner cites column 6,lines 13-17 of Wu in support of this interpretation. However, this section of Wu only indicates that these microstructures ("craters 200") engage the passageway of the lumen of a blood vessel when the stent is deployed. No teaching or suggestion is made that these structures are "raised out of the implant surface to such an extent that ... the microcannula penetrates into the media of the blood vessel" as recited in claim 1. Wu merely teaches that the "craters" "can be used to deliver therapeutic substances from the stent directly to the lumen wall..." (column 2, lines 60-62). As shown in Fig. 1 and as explained in the accompanying description in paragraph 0034 of the present application, the wall of an artery contains three layers: the intima 16 which is bounded by an inner elastic membrane 20 and a basal lamina 18 underlying endothelium cells 14; the media 22; and the adventitia 28. While Wu provides a stent that includes structures that allow delivery of a therapeutic substance directly to the wall of the vessel, contrary to the Examiner's statement regarding column

6, lines 13-17, Wu does not teach or suggest microcannulae that penetrate into the vessel wall. Wu merely provides that the protruding structures or craters "engage the lumen of the passageway ... to help prevent the stent from slipping out of the treatment site." Column 6, lines 15-17. Wu does not teach or suggest structures that penetrate into the vessel past the endothelium, the basal lamina, and the inner elastic membrane and allow delivery of such substances directly into the media. Additionally, Wu's terminology (i.e. "craters") for these structures further indicates that Wu does not intend for these structures to act as microcannulae as in the present invention. Rather, the structures are merely intended to engage and secure the stent to a vessel or to a cover for the stent.

The Examiner also cites column 11, lines 63-66 of Wu as disclosing microcannulae having a diameter and length of 100 μm. However, this is a misreading of Wu's disclosure. While the depth 220 of Wu's craters may extend to as much as 100 μm (column11, lines 65-66), this distance is measured from the top of the lip 204 of the crater to the bottom surface 210 of the crater (column 5, lines 21-23) and includes arrangements where the bottom of the crater 210 is beneath the stent surface plane 114 as shown in Fig. 2B of Wu (see also column 5, lines 41-44). In contradistinction, the length of the microcannulae of the present invention is measured from the surface of the stent facing the vessel wall (paragraph 0036). A correct comparison of the lengths of the structures of Wu to those of the present invention would be a comparison of the length of the lip height 218 of Wu's craters, 10-80 μm (column 11, lines 65-67), to the microcannulae of the present invention.

Therefore, the Applicants maintain that Wu does not teach or suggest all of the elements of claim 1, namely, a stent having a microcannula that penetrates into the media of a blood vessel when the stent bears against the wall of the blood vessel, and that the Examiner has not established a *prima facie* case of anticipation of claim 1. As shown above, claim 1 patentably distinguishes over Wu. Likewise, claims 2, 5-13, and 26-29, which directly or indirectly depend from claim 1, and contain all the limitations of claim

1 also patentably distinguish over Wu. Withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

Claims 3 and 4 stand rejected as obvious over Wu. Claims 14 and 15 stand rejected as obvious over Wu in view of Hossainy. To establish a *prima facie* case of obviousness, three requirements must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.) The Applicants maintain that these requirements have also not been met and that the Examiner has not established a prima facie case of obviousness with respect to these claims.

First, neither Wu nor Hossainy, either independently or in combination, teach or suggest a stent having a microcannula that penetrates into the media of a blood vessel when the stent is bears against the wall of the blood vessel, as detailed above. Additionally, one of ordinary skill in the art would not have found any suggestion or motivation to modify the length of the craters of Wu to 100-400 μm, or to 150-300 μm, or to 180-250 μm, or to any other length. Contrary to the Examiner's assertions, the Applicants have provided a distinct advantage of the claimed microcannula length ranges, namely, to deliver therapeutic products directly into the media of blood vessels, not just to the interior surface of the blood vessels. Neither Wu nor Hossainy provide any teaching or suggestion that such delivery is desirable or possible. Therefore, the Applicants maintain that the Examiner has not established a *prima facie* case of obviousness of claims 3, 4, 14, and 15, which patentably distinguish over Wu, either alone or in combination with Hossainy. Withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

The outstanding Office action was mailed on 8 June 2005 and a response is timely if filed on or before 8 September 2005. No fees are believed to be due with the filing of this response. However, in the event that a fee for the filing of this response is insufficient, the Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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